

IN THE CLAIMS

1. (Currently amended) A controlled release pharmaceutical tablet composition ~~comprising nimesulide~~ for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition , one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, said nimesulide being present in the fast release layer and in the extended release layer.
2. (Currently Amended) A controlled release pharmaceutical tablet composition of nimesulide as claimed in claim 1 which comprises nimesulide as an active drug from 20% to 70% w/w of the tablet composition, one or more release controlling materials from 5% to 65% w/w of the tablet composition and pharmaceutical excipients from 10% to 70% w/w of the tablet composition.
3. (Cancelled)
4. (Currently Amended) A controlled release pharmaceutical tablet composition of nimesulide as claimed in claim 1 wherein the release controlling materials are selected from the group consisting of cellulose and cellulose derivatives, waxes, carbomers, polyalkylene polyols, polycarbophils, methacrylic acid copolymers, gelatins, gums, and polyethylene oxides, or a combination thereof.
- 5.(Currently Amended) The composition as claimed in claim 1 wherein the fast release layer, the extended release layer or both which further comprise comprises modifiers selected from the group consisting of wetting agents, solubilizers, surfactants, plasticizers, pore formers, pH modifiers and tonicity adjusting agents, or a combination thereof.
- 6.(Previously presented) A controlled release pharmaceutical tablet composition as claimed in claim 1 which is a gastroretentive system wherein the residence time of the drug is increased in the stomach, duodenum, jejunum or ileum.

7. Previously presented) The tablet composition as claimed in claim 6 wherein gastroretention of nimesulide is achieved by mucoadhesion, flotation, reducing gastrointestinal motility, or a combination thereof.

8. (Currently Amended) The tablet composition as claimed in claim 7 wherein the extended release layer comprises polymers having affinity for gastrointestinal mucosa, mucoadhesion is achieved by treating nimesulide with polymers having affinity for gastrointestinal mucosa said polymers selected from the group consisting of polycarbophils, carbomers, alginates, cellulose and cellulose derivatives, chitosan, gums and lectins, or a combination thereof to achieve mucoadhesion.

9. (Currently Amended) The tablet composition as claimed in claim 7 further comprising in the fast release layer, extended release layer or both ~~wherein flotation is achieved by adding to the composition~~ gas-generating materials selected from the group consisting of sodium bicarbonate, sodium carbonate, calcium carbonate and potassium carbonate alone or in combination with an acidic substance selected from the group consisting of hydrochloric acid, citric acid, fumaric acid, malic acid, maleic acid, ascorbic acid and tartaric acid, or a combination thereof to achieve flotation.

10. (Currently Amended) The tablet composition as claimed in claim 7, wherein the material for reducing gastrointestinal motility is reduced by using materials ~~is selected from the group consisting of fats, fatty acids and transesterification products of fats and fatty acids with polyols,~~ or a combination thereof.

11. (Currently Amended) A process for the manufacture of a controlled release tablet composition ~~of nimesulide~~ for peroral administration consisting of ~~comprising~~ a single unit fast release layer and a single unit extended release layer which comprises mixing together nimesulide as an active drug up to 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition said nimesulide being present in the fast release layer and in the extended release layer.

12. (Canceled)

13. (Canceled)

14. (Canceled)

15. (Currently Amended) The controlled release pharmaceutical tablet composition of nimesulide as claimed in claim 2 wherein the release controlling materials are selected from the group consisting of cellulose and cellulose derivatives, waxes, carbomers, polyalkylene polyols, polycarbophils, methacrylic acid copolymers, gelatins, gums and polyethylene oxides, or a combination thereof.

16. (Canceled)

17. (Canceled)

18. (Canceled)

19. (Currently Amended) The composition according to claim 1 wherein the fast release layer comprises nimesulide and one or more pharmaceutical excipients selected from diluents, binders, wetting agents, disintegrants and lubricants; or a combination thereof and the extended release layer comprises nimesulide and release controlling material.

20. (Canceled)

21. (Canceled)

22. (Canceled)

23. (Canceled)

24. (Canceled)
25. (Currently Amended The composition according to claim 1 ~~claim 18~~ further comprising a coating.

26. (new) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the fast release layer comprises nimesulide, lactose, starch, colloidal silicon dioxide, polyvinylpyrrolidone, polyoxyethylene sorbitan monostearate, docusate sodium, magnesium stearate and croscarmellose sodium; and the extended release layer comprises nimesulide, lactose, polyvinylpyrrolidone, magnesium stearate, docusate sodium, hydroxypropyl methylcellulose, colloidal silicon dioxide and sodium lauryl sulphate.

27. (new) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the fast release layer comprises nimesulide, lactose, starch, colloidal silicon dioxide, polyvinylpyrrolidone, polyoxyethylene sorbitan monostearate, docusate sodium, magnesium stearate and croscarmellose sodium.

28. (new) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical

excipients from 0% to 90% w/w of the tablet composition, wherein the extended release layer comprises nimesulide, lactose, polyvinylpyrrolidone, magnesium stearate, docusate sodium, hydroxypropyl methylcellulose, colloidal silicon dioxide and sodium lauryl sulphate.

29. (new) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the fast release layer comprises nimesulide, polyvinylpyrrolidone, magnesium stearate and croscarmellose sodium.
30. (new) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the extended release layer comprises nimesulide, polyvinylpyrrolidone, magnesium stearate and hydroxypropyl methylcellulose.